

I. Summary of Safety and Effectiveness - 510(k) Summary

W.O.M. GmbH
Kaiserin-Augusta-Allee 113
D-10553 Berlin
Germany.

Proprietary Name: Arthro-Surgimat-A103

Common Name: Arthroscopic Pump

The ARTHRO-SURGIMAT-A103 is a high flow arthroscopic pump intended to distend joint cavities. The ARTHRO-SURGIMAT-A103 is a modified version of and substantially equivalent to the device Arthro-Surgimat-1500 (K983910) manufactured by W.O.M. GmbH. W.O.M. also claims substantial equivalence to the Apex Universal Irrigation System (K933873).

With the exception of the following modifications, the ARTHRO-SURGIMAT-A103 incorporates the same design features and accessories as the Arthro-Surgimat-1500 (K983910):

- **SINGLE PRESSURE SENSOR**

The ARTHRO-SURGIMAT-A103 no longer incorporates two pressure sensors. The ARTHRO-SURGIMAT-A103 incorporates a single ceramic sensor in place of the redundant pressure measurement of the predicate device. The redundant pressure measurement (two sensors) of the predicate device was required because the long-term stability of the viton membrane sensors could not be guaranteed. Accordingly, two sensors monitored pressure measurement. If a difference of > 50 mmHg were detected, a failure alarm was activated.

With the ceramic sensor, redundant pressure measurement is no longer required. Unlike the viton membrane sensors of the predicate device, the long-term stability of the ceramic sensor has been verified and certified by the sensor manufacture and W.O.M. GmbH ($< \pm 0,4 \% \text{ p.a.} = < 8 \text{ mbar p.a.}$). This value represents an improvement over the 50 mmHg sensor drift threshold of the predicate device. Moreover, the ceramic sensor has a voltage level (Spannungspegel) of 0,5 volt in a loaded and unloaded state. Should the ceramic sensor rupture, the voltage level is lost and the sensor failure is detected by the device.

All pressure safety features and thresholds of the Arthro-Surgimat-1500 (K983910) have been maintained.

- **PROGRAM KEYS**

No program keys are available with this version of the device.

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The utility and safety of arthroscopic techniques using modern electronic high flow pumps is discussed in the following literature, including the benefits and risks of such procedures and the importance of effective, well maintained instrumentation.

A Comprehensive discussion of the use of distention methods is presented in the book "Arthroscopie: Diagnostika und Therapie" (1) by Harald Hempfling, 1995, in which the development of arthroscopic procedures is reviewed, including objective comparisons of arthroscopy vs. traditional methods of treatment. This extensive analysis of the instrumentation in this field includes comments on the use of modern high flow pumps, the selection of the optimal distention medium and a summary of other instruments necessary for arthroscopic procedures. (pg. 13-41).

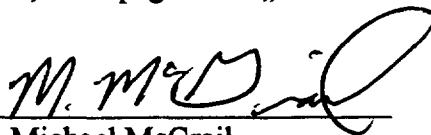
This work is of particular interest due to the extensive review of arthroscopic techniques specific to various joints. This includes, but is not limited to, the knee, shoulder, wrist, and elbow.

„Operative Arthroscopy, Second Edition“ (2), provides an in-depth review of the history, techniques and modern apparatus of arthroscopic procedures. Of special interest is the chapter on advanced arthroscopic instrumentation (pg. 7-13), in which irrigation systems are also discussed in detail. Other references to irrigation systems include pg. 75 and pg. 256.

REFERENCES

1. Hempfling, Harald. "Arthroscopie: Diagnostika und Therapie". Landsberg, Germany: Ecomed Verlagsgesellschaft AG + Co. KG, 1995, 375 pages.
2. McGinty, John B. "Operative Arthroscopy, Second Edition" Philadelphia: Lippincott-Raven Publishers, 1995, 1500 pages. See „Advanced Arthroscopic Instrumentation“ on pages 7-13.

Signed:


Michael McGrail
Agent, W.O.M. GmbH

Date: 01/14/00



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 18 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

WOM GmbH
c/o Mr. Michael McGrail
Regulatory Consultant
194 Branch Street
Mansfield, Massachusetts 02048

Re: K000153
Trade Name: Arthro-Surgimat A103
Regulatory Class: II
Product Code: HRX
Dated: January 12, 2000
Received: January 18, 2000

Dear Mr. McGrail:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

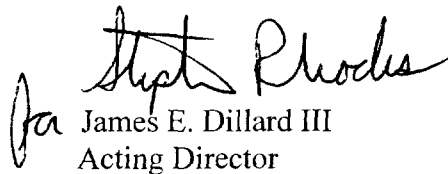
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,


James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

CONFIDENTIAL

APPLICANT: W.O.M. GmbH
510(K) NUMBER (if known): K000153
DEVICE NAME: ARTHRO-SURGIMAT A103

INDICATIONS FOR USE:

The ARTHRO-SURGIMAT-A103 is a high flow arthroscopic pump intended for fluid distention of the knee, shoulder, elbow, ankle and wrist joint cavities during arthroscopic procedures. (21 C.F.R. & 888.1100).

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Steph Rhoda
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000153

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Prescription Use X
(Per 21 CFR 801.109)

Over-the-Counter Use _____